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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,845

10/15/2003

Michael T. Lotze

UPT-004

9535

22428

7590

10/18/2007

FOLEY AND LARDNER LLP

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,845

Applicant(s)

LOTZE ET AL.

Examiner

Amy E. Juedes, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 31 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 8/7/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/07 has been entered.

Claims 28-29, 31, and 35 have been amended.

Claims 32-34 have been cancelled.

Claims 1-31 and 35 are pending.

Claims 1-26 and 30 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 27-29, 31, and 35 are under examination.

2. The rejection of the claims under 35 U.S.C. 112 second paragraph is withdrawn in view of Applicant's amendment to the claims.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 27-29, 31, and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bhardwaj et al., 1996, as evidenced by Hackstein et al., 2002.

As set forth previously, Bhardwaj et al. disclose a culture (i.e. a composition) comprising ex-vivo purified dendritic cells and IL-12 (see pg. 715 and Table 1 in particular). As evidenced by Hackstein et al., dendritic cells arise from CD34+ stem cells, and thus the ex-vivo isolated dendritic cells taught by Bhardwaj et al. are CD34+ derived. It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Bhardwaj et al. (RPMI supplemented with gentamicin, human serum and HEPES buffer) is not

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incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Applicant's arguments, and declaration of Inventor Lotze filed 6/29/07 have been fully considered, but they are not persuasive.

Applicant argues, and provides a declaration by Inventor Lotze stating that physicians and medical researchers would not consider the cell cultures disclosed by Bhardwaj to be a therapeutic composition, nor would one skilled in the art consider said cultures "compatible with physiological conditions".

It is the Examiner's position that cells in culture are considered to be compatible with physiological conditions and not incompatible with pharmaceutical use. Absent a limiting definition of "therapeutic composition", cells in culture are encompassed by the broadest reasonable definition of "therapeutic composition". In fact, the instant specification discloses on page 15 that the composition of the invention may be administered in any physiological solution. As noted above, the cell culture medium taught by Bhardwaj is compatible with physiological conditions, and thus meets the limitations of a "therapeutic" composition.

5. Claim 27-29, 31, and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kelleher et al., 1998.

As set forth previously, Kelleher et al. disclose a culture (i.e. a composition) comprising dendritic cells and IL-12 (see pg. 750 in particular). Kelleher et al. further teach that said dendritic cells are derived from CD34 bone marrow stem cells (see abstract and pg. 750 in particular). It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Kelleher et al. (RPMI supplemented with penicillin, streptomycin, glutamine, FCS, and 2 mercaptoethanol) is not incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Applicant's arguments, and declaration of Inventor Lotze filed 6/29/07 have been fully considered, but they are not persuasive.

Applicant argues, and provides a declaration by Inventor Lotze stating that physicians and medical researchers would not consider the cell cultures disclosed by Kelleher to be a therapeutic composition, nor would one skilled in the art

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consider said cultures "compatible with physiological conditions".

It is the Examiner's position that cells in culture are considered to be compatible with physiological conditions for the same reasons set forth about.


6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600


9/27/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER